Module 9b: Other Compliance/Noncompliance—HACCP Systems

Goal To provide instructions to in-plant inspection personnel for determining an establishment's compliance with HACCP, SSOP, Salmonella, and other nonrelated HACCP and pathogen requirements.

Objective After completing this module, participants will be able to:

1. Define what "Other Compliance/Noncompliance" means.

2. Be able to apply the HACCP inspection system procedures.

3. Be able to document findings and take enforcement actions when HACCP inspection system procedures are not met.

Introduction

Industry is responsible for developing, implementing, and maintaining effective HACCP systems to assure food safety.

The FSIS role will be one of regulatory oversight. Industry will be held accountable for maintaining adequate HACCP systems.

Inspection personnel will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the regulatory requirements. The various Agency verification activities may include:

- Reviewing the HACCP plan;
- Reviewing the CCP records;
- Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;
- Reviewing the critical limits;
- Reviewing other records pertaining to the HACCP plan or system;
- Direct observation or measurement at a CCP;
- Sample collection and analysis to determine the product meets all safety standards; or
- On-site observations and record review.

As stated earlier, in-plant inspection personnel will review an establishment's HACCP plan upon initial implementation, or anytime it's modified upon reassessment, to determine its compliance with regulatory requirements. This is the basic compliance/noncompliance component of the regulatory oversight model. In addition to the basic compliance/noncompliance check, special teams of FSIS personnel, working closely with in-plant inspection personnel, may conduct the special verification component of the regulatory oversight model.

After the basic compliance check of the HACCP plan, in-plant inspection personnel will focus on the day-to-day or ongoing operation of the establishment's HACCP system. Inspection personnel will make determinations about the HACCP system including whether the system prevents the production or shipment of adulterated product. This is the "other requirements" compliance/noncompliance component of the regulatory oversight model.

Other Requirements Compliance/Noncompliance HACCP Procedures

Once the establishment's HACCP plan has met the basic requirements, inspection personnel will perform inspection procedures as indicated in block 7 of the regulatory process model/flow diagram (Attachment 1).

There are only two "**other requirements**" ISP guide procedures for a particular HACCP activity because the procedures in elements 03B through 03J are identical. Only the code is different. In other words, 03B01 is the same procedure as 03C01, 03D01, etc. Likewise, 03B02 is the same procedure as 03C02, 03D02, etc. The different procedures are for the different HACCP plans required for the nine specific processes listed in regulations 417.2(b)(1). The purpose of these procedures is to determine if the establishment meets the five features or requirements. The five requirements are **monitoring, verification, recordkeeping, corrective actions, and reassessment**.

The establishment normally takes corrective actions or performs a reassessment in response to a deviation or change in the process. Inspection personnel will routinely verify the monitoring, verification, and recordkeeping requirements. However, corrective actions in response to a deviation are essential parts of the HACCP plan. **Anytime** a deviation is determined at monitoring, verification, or recordkeeping, you **always** verify that the corrective action requirements are met.

We will talk about these procedures as 01 and 02. Because some of the requirements have records associated with them, both 01 and 02 have two components—**review and observation** and **recordkeeping**. Both 01 and 02 can be used to verify each of the five requirements. The method used to perform the procedure is **one** difference between them. Under each requirement we will describe what is expected with each procedure.

The 01 procedure is for reviewing a **random sample** of the HACCP regulatory requirements in operation. Using the review and observation and/or recordkeeping component, any combination of the requirements can be randomly verified. It would be equally appropriate to focus on one of the requirements specifically while performing 01. For example, an inspector may decide to observe a plant employee measuring a critical limit and recording the result. The inspector may then measure the critical limit and compare his or her finding with the limit that the employee recorded. He or she may also review CCP records for a different lot or lots of product and/or calibration records before considering the procedure complete.

The 02 procedure is used to determine that the establishment is following the HACCP plan, establishment personnel perform tasks in the plan, corrective actions are taken, and pre-shipment review prevents adulterated product for a given lot or shipment. For 02, you can use review and observation and/or recordkeeping, but in this case you must **verify all requirements**.

It is important to point out that because 01 is **random**, it is making a determination if the plant meets the HACCP regulatory requirements. Because 02 looks at an entire given lot or shipment, you are additionally determining if the HACCP plan prevented distribution of adulterated product.

This means that the inspector will verify monitoring at each CCP, each CCP verification activity performed, the corrective action (if any) taken in response to a deviation, any reassessment conducted in response to a deviation, and the pre-shipment review for that specific production lot or shipment. The 02 procedure is not considered complete until after the inspector has verified the establishment's pre-shipment review. Therefore, performing the 02 procedure may take some time depending on the process.

If while performing 01, you determine noncompliance with the HACCP regulatory requirements, you would want to further verify if the plan prevented adulterated product from being shipped. To do this you will perform an 02 **anytime** noncompliance is found on 01. When performing the 02, you will want to focus on very specific parts of the requirements.

Flowcharts (Attachment 2) identify the five requirements of the HACCP system that are verified by inspection personnel when they perform HACCP procedures 01 and 02. A reference cite from FSIS Directive 5000.1 has been provided for each requirement.

The following is a discussion on the review and observation and recordkeeping components of the 01 and 02 procedures.

Reviewing and Observing Establishment Operations

Since both HACCP procedures have a review and observation component, inspection personnel will need to know how to perform a review and observation.

Inspectors will verify that the establishment is doing what it says it is doing in its HACCP plan by observing the activities occurring in production areas. They will determine whether the monitoring, corrective action, verification, recordkeeping and reassessment procedures contained in the HACCP plan are being accomplished, and that the plan is otherwise being followed by:

- Performing on-site tests such as taking temperatures of product after cooking, temperatures of coolers or carcasses in coolers, temperatures of chill water, etc., to determine if the CCP as defined in the plan is under control and compare inspection results to HACCP plan records;

- Directly observing an establishment employee performing an activity such as taking temperatures, calibrating monitoring equipment, taking corrective action, etc., to determine if the plant is following the HACCP plan and recording measurements accurately and promptly.

Reviewing Recordkeeping

Since both HACCP procedures have a recordkeeping component, inspection personnel will need to know how to perform the recordkeeping component. We will discuss general recordkeeping; later we will discuss specifics.

Inspection personnel should conduct record reviews in an organized manner such as depicted in the following flow chart:

ISP guide procedure/FSIS Directive/Regulations [HACCP Plan]
↓
Select/assemble appropriate records
↓
Determine if requirements are met

Selecting Records

- The *type* of records selected will depend on the inspection procedure to be performed.

- The *number* of records selected will depend on the number of available records and the procedure you are performing.

  When performing the 02 procedure, inspectors should select complete record sets for a **specific production lot or shipment**. Looking at the CCP monitoring, corrective action and verification records for a particular production lot gives inspectors a complete picture of the establishment operations for that lot. If a problem is uncovered during record review that the inspector believes may affect other product lots as well, he or she should also select records for those other lots for review. The inspector's goal should be to determine whether the problem is an isolated event, or if it represents a pattern of noncompliance over time, and across product lines.

- **Inspection personnel should not select records that have been previously examined. When performing the 02 procedure, however, inspectors may end up reviewing some records they reviewed while performing the 01 procedure. Remember that the 02 procedure requires the inspector to review the records for an entire lot through the entire process, so he or she may have reviewed the monitoring records for the lot early in the process.**

Thorough record review is critical to the overall effectiveness of FSIS verification activities. Records may be used to show that the establishment is not meeting the requirements of its HACCP system and to support additional regulatory action.

HACCP Plan Requirements

Again there are five requirements for the establishment's HACCP plan that inspectors will verify through the performance of PBIS procedures. They are:

- **Monitoring;**
- **Verification;**
- **Recordkeeping;**
- **Corrective Actions; and**
- **Plan Reassessment.**

Let's walk through each requirement and then discuss the inspector's responsibilities for the review and observation and recordkeeping components of the procedures used to verify each of the five requirements.

Monitoring

Monitoring is an integral part of HACCP. Monitoring by the establishment is usually performed using physical or chemical measurements or by observation. The establishment must correctly document all observations and measurements of a CCP.

Establishment Responsibilities

Part Two of FSIS Directive 5000.1 addresses the HACCP regulatory requirements.

FSIS Directive 5000.1 III. B. 1 identifies the establishment's responsibilities for monitoring its CCP established in the HACCP plan.

III. B. 1 a. of FSIS Directive 5000.1 requires the establishment to monitor its CCP's to ensure compliance with critical limits (§ 417.2©(4)).

III. B. 1 b. of FSIS Directive 5000.1 requires the establishment to provide a recordkeeping system to document the monitoring of the CCPs. The records are to contain actual values (in terms of the times, and observations, temperatures, and/or other quantifiable limits in the HACCP plan) obtained during monitoring (§417.2©(6) and 417.5(a)(3)).

Inspection personnel perform both the 01 and 02 inspection procedures to verify the establishment's monitoring requirements are met. Each of the two procedures has a review and observation component and a recordkeeping component.

Review and Observation

Inspection personnel will determine if the establishment's monitoring is performed as described in the HACCP plan. To make this determination, they will need to become very familiar with how the establishment intends to monitor each CCP. This would include knowing the method and frequency of measuring the critical limit(s).

> For example, the HACCP plan states that a plant employee will measure the internal temperature of a product unit from three different locations (cold spots) within the cooking unit and record the lowest reading observed. Inspectors will observe the employee taking the internal temperature measurements to verify that he or she is following the HACCP plan, and not just taking one internal temperature measurement and recording it. Likewise, if the HACCP plan states that an employee will measure the pH of a mixture of the liquid and solids portion of the product, inspectors will observe the employee taking the pH measurement to verify that the employee is correctly measuring it, and not just placing the pH probe in only the liquid portion and recording a result.

Inspection personnel will determine if monitoring is performed at the required frequency stated in the HACCP plan.

> For example, if the HACCP plan calls for hourly monitoring, inspectors will observe monitoring at the CCP to verify that an employee actually takes a measurement hourly.

Inspection personnel will determine if the establishment's monitoring results are accurately and promptly recorded. Monitoring results must be recorded at the time the specific event occurs.

> For example, inspection personnel observe the readings on monitoring equipment or performs on-site measurements to see if their values correspond with what the establishment has recorded. At the same time, they should verify that the critical limit is met. For example, if the battering and breading **temperature** was identified as a CCP in the HACCP plan, the inspector may observe the dial thermometer on the batter and breading holding vat, or take the internal temperature. Then compare the finding to what the plant employee has recorded on the batter and breading temperature record.

Recordkeeping Component

Inspection personnel will determine if:

- The observations, tests or measurements are recorded at the required frequency.
- All the required data has been recorded.

- The data is accurate, e.g., if calculations are required, are they performed as stated in the HACCP plan.

- The critical limits have been met.

- Corrective action has been taken when necessary (If yes, go to corrective action requirement).

01 versus 02 Procedures

Determining compliance/noncompliance for the monitoring requirement of the establishment's HACCP plan will be done on a **random** basis when performing the 01 procedure. For example, inspectors may determine compliance/noncompliance of the establishment's monitoring for one or more CCPs for a **particular lot of product**, or several CCPs for different lots of product within a process. When inspectors perform the 02 procedure, the monitoring requirement for all CCPs of that specific production lot or shipment will be verified through the review and observation component and/or recordkeeping component of the 02 procedure.

Note: Whenever the results of an establishment's monitoring activity indicate that corrective action was taken in response to a deviation from a critical limit, this should be a trigger mechanism for the inspector to verify the corrective action requirement. If found while performing the 01 procedure, they should continue performing the 01 procedure to determine the compliance/noncompliance of the corrective action that establishment has taken. On the other hand, if they found that corrective action was taken in response to a deviation from a critical limit while performing the 02 procedure, they would have to determine the compliance/noncompliance of the corrective action that the establishment has taken for that specific production lot or shipment. The review and observation and/or recordkeeping component of the inspection procedure could be used.

If inspection personnel find noncompliance while performing either the 01 or 02 procedure, the "Monitoring" trend indicator is marked on the NR and PS.

Verification

As you know, inspection personnel perform verification or oversight activities. For HACCP, the establishment also is required to perform verification of their HACCP plan(s). Ongoing verification by the establishment includes such activities as calibration of process-monitoring instruments, direct observations of their monitoring activities, corrective actions, and the review of their records generated for the HACCP plan(s). The verification activities listed in the HACCP plan will dictate what inspection personnel will do when performing the procedures for this requirement.

Establishment's Responsibilities

FSIS Directive 5000.1 III. B. 2 describes the regulatory requirements for the establishment's ongoing verification activities/procedure it intends to perform to verify the implementation of its HACCP plan.

III. B. 2 a. of FSIS Directive 5000.1 identifies the regulatory requirement that the establishment must verify the implementation of its HACCP plan(s) by performing verification activities. These procedures, including their frequency, are to be identified in the HACCP plan (§417.2©(7) and 417.4 (a)(2)).

III. B. 2 b. of FSIS Directive 5000.1 identifies the regulatory requirement that the establishment must maintain records that document its verification activities. Establishment records documenting verification activities include—

- ★ ***The calibration of process-monitoring instruments, and***
- ★ ****Actions taken in response to a deviation from a critical limit (including a deviation not covered by a specific corrective action in the HACCP plan) (§ 417.3© and 417.5(a)(3)).*** **[See corrective action]**

III. B. 2 c. of FSIS Directive 5000.1 states "if an establishment that slaughters cattle, swine, chickens, or turkeys has substituted an alternative frequency for the frequency of sampling for E. coli specified in § 310.25 (a)(2)(iii) or § 381.94(a)(2)(iii), the alternative is an integral part of the establishment's verification procedures (paragraph (a)(2)(iv) of §310.25 or § 381.94; see Part Four, Paragraph III.B.1.d)".

Again, the inspector's verification will depend upon the type and frequency of the establishment's verification activities described in the HACCP plan. CCP verification, auditing, product testing or sampling activities should be verified by inspection personnel more often than other verification activities e.g., equipment calibration activities. Since calibration activities are not lot-specific, these activities should be verified randomly while performing the 01 procedure.

Inspection personnel perform both the 01 and 02 procedures to verify the establishment's verification requirements are met. Both the 01 and 02 procedures have a review and observation and recordkeeping component.

Review and Observation

Inspection personnel will need to become familiar with how the establishment intends to determine that its HACCP system is functioning as intended. They will observe plant employees performing verification activities. Inspection personnel will determine that verification activities are performed at the frequency stated in their HACCP plan and the results are recorded at the time of verification.

Inspection personnel will determine if product testing (if applicable) is performed as stated in the HACCP plan. Inspection personnel will determine if the establishment is calibrating its monitoring equipment as stated in the HACCP plan.

For example, they will determine that the mercury-in-glass, time/temperature recorder, or hand-held thermometer is calibrated at the frequency stated in the plan, and that it is calibrated in accordance with the manufacturer's instructions, e.g.,

correct test method and correct standard used. To make this determination, they will have to observe the calibration being performed. For example, if the plan states that the hand-held digital thermometers for measuring the internal temperature of meat patties will be calibrated daily, inspectors should observe the calibration procedure when performing the 01 procedure. When in operation, inspectors verify that mercury-in-glass thermometers don't have divided columns, time/temperature recorders are accurately keeping time, etc.

Recordkeeping Component

Keep in mind that some establishment verification procedures will not require the plant to create a new record, but rather to examine and initial and date an existing record.

Inspection personnel will determine if:

- Product testing or sampling, record reviews, other audits, and calibrations are performed at the frequencies specified in the HACCP plan.

- Corrective action has been taken when necessary (If yes, go to corrective action requirement).

  For example, if during calibration, the processor determined that an oven's temperature sensing probe was registering too high, did management adjust the thermometer? Did management evaluate the oven temperature monitoring records generated since the last calibration, adjusting for the instrument error? If the adjustment reveals that the critical limit was exceeded, did management perform the corrective actions prescribed in their HACCP plan.

01 Versus 02

If an establishment includes an alternate *E. coli* frequency in their HACCP plan, inspection personnel will also determine if the establishment meets their HACCP plan.

In addition to the 01 procedure being random, if the establishment has an alternate sampling plan for *E. coli*, it will be verified under the 01 procedure. The 02 procedure is for a specific production lot or shipment.

The following is an example of what an establishment might include in its HACCP plan as an alternative sampling frequency for *E. coli* that the inspector would verify using the 01 procedure.

A beef slaughter establishment's HACCP plan might state that they will sample at the rate of 1 test per 1000 carcasses rather than one test per 300 carcasses required by FSIS. To support this frequency change, in addition to testing chilled carcasses as required by the regulations, they will also sample at the CCPs for sanitary dressing. The establishment will sample at the opening cut, tying the bung, at the final wash and in the cooler. At each consecutive sampling site the results are reported in

CFU/cm^2. The critical limit is equivalent to the FSIS requirement. The establishment has included a verification activity in their HACCP plan for the *E. coli* sampling.

If inspection personnel have questions concerning the establishment's alternate sample frequency for *E. coli* they should contact the TSC.

Note: Whenever the results of an establishment's verification activity indicate that corrective action was taken in response to a deviation from a critical limit, this should be a trigger mechanism for the inspector to verify the corrective action requirement. If found while performing the 01 procedure, they should continue performing the 01 procedure to determine the compliance/noncompliance of the corrective action that the establishment has taken. On the other hand, if they found that corrective action was taken in response to a deviation from a critical limit while performing the 02 procedure, they would have to determine the compliance/noncompliance of the corrective action that the establishment has taken for that specific production lot or shipment. The review and observation and/or recordkeeping component of the inspection procedure could be used.

If inspection personnel find noncompliance while performing either the 01 or 02 procedure, the "Verification" trend indicator is marked on the NR and PS.

Recordkeeping

Records are any written or other recorded information, such as electronically stored data on a computer, that the establishment generates to document activities, conditions, test results, etc.

Inspectors will verify that the establishment is doing what it says it is doing in its HACCP plan by reviewing records that document:

- The daily monitoring of the critical limit(s) for the CCPs identified in the HACCP plan such as internal temperature records, chiller temperature records, etc.

- Any corrective action taken such as CCP deviation reports/log

- The establishment's verification activities such as:

  Records that document the results of the direct observation of monitoring activities, corrective actions, and the review of records generated by the HACCP plan. These are sometimes called CCP verification reports and audit reports.

  Process-monitoring instrument calibration records

  Validation/HACCP plan support documents

- Other verification records as specified in the HACCP plan, e.g., chemical and microbiological product testing or laboratory results, and alternate *E. coli* testing.

FSIS views recordkeeping as a serious matter with potentially grave implications if records are falsified or not properly maintained. When enforcement action is required, it is important to determine errors that reveal a pattern of noncompliance with the HACCP plan, willful errors or omissions, or intentional misinformation. Take, for example, the difference between a record that shows a deviation, such as an inadequate thermal cycle, with one that shows that a monitoring activity was not performed at the required frequency. Although both conditions reflect a failure to meet regulatory and/or plan requirements, the former **may** indicate an inadequate HACCP system if not detected and corrected by the establishment, where as the latter is a trend.

When inspection personnel verify the recordkeeping requirement for the establishment's HACCP plan, they will only perform the recordkeeping component of the HACCP procedures. In other words, no review or observation of operations is necessary.

Establishment Responsibilities

FSIS Directive 5000.1. III. B. 5. (a-f) describes the recordkeeping requirements that the establishment must meet for its HACCP plan.

FSIS Directive 5000.1. III. B. 5. a. addresses the requirement that the establishment must have documentation that supports the HACCP plan. (§ 417.5(a)(2)). This is scientific, technical, or regulatory data that supports the plant's selection of each CCP, critical limit, monitoring procedure, and verification procedure, and the frequency with which the plant conducts those monitoring and verification procedures.

FSIS Directive 5000.1. III. B. 5. b. addresses the requirement for product identification. Establishment records document slaughter production lot, product code(s), product name, or other identifier such as a bar code (§ 417.5(a)(3)).

FSIS Directive 5000.1. III. B. 5. c. addresses the requirement for record authentication. Each entry on a record must be made at the time the specific event occurs and includes the date and time that the entry was made. For purposes of authenticity, the establishment's records are required to be initialed and dated by the establishment employee. (§417.5(b)).

FSIS Directive 5000.1. III. B. 5. d. addresses the requirement for data integrity. The establishment must have methods of ensuring the integrity of HACCP plan records maintained on computers. (if any) (§417.5(d)).

FSIS Directive 5000.1. III. B. 5. e. addresses the requirement for the pre-shipment review. HACCP records associated with the production of a lot of product must be reviewed, if practicable, by an establishment employee other than the one that produced the record before the product is distributed in commerce. This reviewer, preferably a HACCP-trained individual, will ensure the records are

complete, critical limits were met, and proper product disposition was made if corrective action was needed. Then record the time, date, and sign the records (§ 417.5©).

FSIS Directive 5000.1. III. B. 5. f. addresses the requirement for record retention and availability. The hazard analysis, HACCP plan, and HACCP plan validation records must be kept at the establishment. CCP monitoring, corrective action, calibration and other verification records must be retained for at least one year if they are for slaughter activities or refrigerated product, and at least two years if they are for frozen, preserved, or shelf-stable products. These records must be kept at the establishment for six months. After that, these records may be stored off-site if they can be retrieved within 24 hours of an FSIS employee's request. § 417.5(a)(3), (§ 417.5(e)(1)),
(§ 417.5(e)(2)).

For example, an establishment is required to have documentation that supports the HACCP plan (417.5(a)(2)).

Establishment X produces cured and smoked poultry breakfast strips. The FSIS regulations for this product (381.150) require that the product reach an internal temperature of 140^0 F. The product must then be cooled to 80^0 F in 1.5 hours and to 40^0 F within 5 hours.

The establishment's HACCP plan for the cured and smoked poultry breakfast stripsindicates that the product will be cooked to an internal temperature of 140^0 F. The plan states that it will be cooled to 85^0 F within 1.5 hours and to 40^0 F within 3 hours. The establishment has utilized a process authority in the development of the cooling curve and has scientific data indicating it is at least equivalent to the FSIS cooling curve for inhibiting microbial growth.

It is also important to note, that the establishment will be required to meet the conditions of the cooling curve in their HACCP plan. That is, they will be required to reach the 40^0 F within 3 hours. Although the 3 hours is less than the FSIS regulatory requirement, it is based on the establishment's cooling curve which allowed them to only reach 85^0 F within 1.5 hours rather than 80^0 F. Therefore, failure to meet the conditions stated in their HACCP plan is documented as noncompliance.

There may be other examples in which the establishment HACCP plan is not identical to the regulation. Based on past experience and knowledge, the inspector may be confident that the differences are at least equivalent to the regulation. For example, an establishment might have scientific data supporting the production of a cooked poultry product with a critical limit of an internal temperature of 150^0 F for 2 minutes at 90% humidity. If the inspector had questions regarding this process, they could contact the TSC for assistance. Another example might be that an establishment plans to produce a cooked poultry product and sets their critical limit at 120^0 F and do not have any scientific or technical evidence to support this internal temperature. In this case, the inspector could withhold inspection and call the DO.

When inspection personnel review CCP monitoring records, verification records, and corrective action records they will determine if the product name or identity, product code or slaughter production lot has been recorded.

When inspection personnel review CCP monitoring records, verification records and corrective action records they will determine if:

- The date and time of the monitoring activity, verification activity, or corrective action have been recorded.

- The signature or initials of the person performing the monitoring activity, verification activity, or taking corrective action are recorded.

Inspection personnel will verify that the establishment has implemented controls to ensure data integrity for computer records, e.g., individual digital signatures, identification passwords, etc. The establishment must have some method of restricting access to the HACCP records so that they can not be tampered with or changed.

FSIS will have access to the HACCP plan, and all records and procedures required by the Pathogen Reduction/HACCP system regulations. Copies of HACCP plans, verification documents, and day-to-day operating records will not be routinely submitted to FSIS, thus inspectors should not possess establishment records.

01 Versus 02

Inspection personnel will verify the HACCP support, product identification, record authenticity, data integrity, and record retention and availability requirements while performing the 01 procedure. For the recordkeeping requirement, only the pre-shipment and data integrity will be verified while performing the 02 procedure. However, monitoring, verification, corrective actions, and reassessment can be verified by using the recordkeeping component of the 02 procedure.

Note: Whenever the results of an establishment's recordkeeping activity indicate that corrective action was taken in response to a deviation from a critical limit, this should be a trigger mechanism for the inspector to verify the corrective action requirement. If found while performing the 01 procedure, they should continue performing the 01 procedure to determine the compliance/noncompliance of the corrective action that the establishment has taken. On the other hand, if they found that corrective action was taken in response to a deviation from a critical limit while performing the 02 procedure, they would have to determine the compliance/noncompliance of the corrective action that the establishment has taken for that specific production lot or shipment. The review and observation and/or recordkeeping component of the inspection procedure could be used.

If inspection personnel find noncompliance while performing either the 01 or 02 procedure, the "Recordkeeping" trend indicator is marked on the NR and PS.

Corrective Action
Deviation from a Critical Limit

Corrective action(s) will be reviewed to ensure that any critical limit deviations found by the establishment during their CCP monitoring, verification activities, and/or pre-shipment review have been addressed as per the HACCP plan, and that the corrective action was documented. Remember that corrective actions for deviations from a critical limit **must** conform to the procedures described in 417.3 of the regulations and **must** be detailed in the HACCP plan.

Establishment's Responsibilities

FSIS Directive 5000.1 III. B. 3 identifies the corrective action that the establishment must take in response to a deviation from a critical limit.

III. B 3 a (1) of FSIS Directive 5000.1 identifies the regulatory requirement for the establishment to assign personnel to be responsible for taking corrective action. The establishment personnel who are responsible for taking corrective action(s) are identifie in the HACCP plan. (§417.3(a)).

III. B 3 a (2) of FSIS Directive 5000.1 requires the establishment to incorporate the corrective actions it intends to take in response to a deviation from an established critica limit into the HACCP plan. The establishment <u>must</u> follow this corrective action procedure(s) (§ 417.2©(5) and 417.3(a).

The establishment <u>must</u> take and document:

- ***The procedures to identify and eliminate the cause of the deviation,***
- ***The procedures to bring the CCP under control,***
- ***Measures established to prevent recurrence, and***
- ***The procedures to prevent distribution of product adulterated as a result of the deviation.***

Review and Observation

The establishment might experience a deviation from a critical limit listed in the HACCP plan. The corrective actions for this deviation **must** be included in the plan. The establishment's corrective action must be sufficient to restore control to the process and ensure that no adulterated product is distributed. Inspection personnel will check the adequacy of the establishment corrective action when there is a deviation from an established critical limit. For example, the inspector may perform on-site tests or observations to verify that the establishment has brought the CCP back under control or observe the plant's procedures for holding and segregating affected product to assure that adulterated product does not enter commerce.

Establishment's Responsibilities

III. B 3 a. (3) of FSIS Directive 5000.1 identifies the regulatory requirement that the establishment must maintain records that document the corrective actions to be taken in response to a deviation from critical limit listed in the HACCP plan. It also identifies exactly what procedures must be documented. **(§ 417.3(a) and (c) and 417.5(a)(3)).**

Recordkeeping Component

Inspection personnel will determine if the corrective actions for each deviation conform to the procedures described in section 417.3 of the regulations and/or the procedures detailed in the HACCP plan.

When establishment management determines that a critical limit has been exceeded during monitoring of a CCP, CCP verification, or pre-shipment review, they must take corrective action. **The four corrective action requirements in 417.3 of the regulations must be met.**

Example documentation for a critical limit deviation:

A swine slaughter establishment has determined that they have a CCP at the final wash in their process. They have set a critical limit for the water pressure of their final wash at 200 psi. The establishment indicates they will monitor this CCP at 60-minute intervals. A deviation at this critical limit occurred. The establishment documentation may look like this:

1) Deviation at the pork carcass final wash. The final wash was less than 200 psi as determined by the 60-minute monitoring. The 10:00 am monitoring check indicated a psi of 210. The psi was 190 at 11:00 am. The carcass chain was stopped until the water pressure was returned to 200 psi. An alarm was installed that rings when the pressure drops below 205 psi. *(Identify and eliminate)*

2) Monitoring at this CCP was increased to 15 minute intervals until the alarm was installed. The alarm was tested at installation to ensure it would work. *(CCP under control after action taken)*

3) Verification includes weekly testing of the alarm system. The HACCP plan is updated to include this verification activity. *(Measures to prevent recurrence)*

4) The affected carcasses, those that went through the final wash cabinet between 10:00 and 11:00 were segregated and treated with a 1 ½% solution of antibacterial lactic acid. *(Procedures to prevent distribution of adulterated product)*

Another example:

The establishment's HACCP plan that covers roast beef has identified the time to chilling as a CCP. The critical limit they have established for this to occur is 90 minutes from the time the product is removed from the cooking unit. A deviation with this critical limit was discovered during the monitoring check. The chilling did not begin until 2 hours after cooking.

The establishment must take and document corrective action according to 417.3. Their documentation might look something like this:

1) The motor on the cooling unit in the roast beef cooler burned out. This was not detected until the first cooling cycle. The motor was replaced. *(Identify and eliminate)*

2) After the motor was installed, the cooler temperature and internal product temperature were monitored every 30 minutes through a complete cooling cycle. *(CCP under control after action taken)*

3) The HACCP Plan has been modified to include checking the cooler temperature before product is placed inside for cooling. The temperature will be monitored every hour on a daily basis. *(Measures to prevent recurrence)*

4) The lot of roast beef was segregated in the second cooler and standard scientific computer software was utilized to plot the cooling curve. The time/temperature indicated the product was adequately cooled to keep microbial growth to a minimum. The cooling cycle was completed and the product shipped. *(Procedures to prevent distribution of adulterated product)*

Corrective Action
Unforeseen Hazard

Corrective action(s) will be reviewed to ensure if any unforeseen hazard is found, the establishment has taken the corrective action described in 417.3 of the regulations and documented those actions on the HACCP records.

Establishment's Responsibilities

III. B 3 b. of FSIS Directive 5000.1 identifies the establishment's responsibilities when a deviation occurs that is not covered by the corrective actions detailed in the HACCP plan.

The establishment must segregate and hold affected product, at least until the establishment:

- ***Performs a review to determine the acceptability of affected product for distribution, and***

- ***When necessary, takes action to ensure the product adulterated as a result of the deviation would not be distributed***

- ***Performs reassessment to determine whether the unforeseen hazard should be included in their HACCP plan***

The procedures used to segregate the product and any corrective action must be documented (§ 417.3(b) and (c) and 417.5(a)(3)).

Review and Observation

Inspection personnel will check the adequacy of the establishment's procedures in response to a deviation from a critical limit that did not have specific corrective actions detailed in the HACCP plan or an unforeseen hazard. For example, the inspector may observe the plant's procedure for holding and segregating affected product to assure that adulterated product does not enter commerce.

Recordkeeping Component

Inspection personnel will verify that the procedures the establishment uses to segregate and hold the affected product and any corrective action taken to ensure that adulterated product was not shipped is documented.

01 Versus 02

In addition to the 01 procedure being random and the 02 procedure being for a specific production lot or shipment, you will generally verify corrective action based on findings from your verification of the monitoring or verifications requirements.

If, while performing the 01 or 02 procedure, the inspector determines that the establishment had to take corrective action in response to an unforeseen hazard deviation, this should be a trigger mechanism for the inspector to verify the plan reassessment requirement.

> Some examples of deviations from a critical limit that the establishment may not have been addressed in their HACCP plan might include dioxin in poultry or an emerging pathogen in ground meat. The dioxin in poultry would be a chemical hazard that would not be likely to recur. An emerging pathogen in ground meat would be a biological hazard that would be likely to occur again.

If inspection personnel find noncompliance while performing either the 01 or 02 procedure, the "Corrective Actions" trend indicator is marked on the NR and PS.

Plan Reassessment

Inspection personnel could verify the reassessment requirement for the establishment's HACCP plan when reassessment is triggered by an unforeseen hazard deviation or second consecutive positive *Salmonella* result.

Establishment Responsibilities

FSIS Directive 5000.1 III. B. 4 a-c defines the regulatory requirements for HACCP plan reassessment and modification.

III. B. 4 a. (1) of FSIS Directive 5000.1 requires the establishment to reassess its plan whenever a deviation that is not covered by a corrective action specified in a HACCP plan occurs, or another unforeseen hazard arises, (§417.3 (b)(4)).

The establishment's plan reassessment will determine if the unforeseen hazard is a hazard that is reasonably likely to occur again in the production process. If it is a hazard that's reasonably likely to occur, then the establishment will have to modify the hazard analysis and the HACCP plan. If it isn't likely to recur, such as dioxin, then the establishment does not have to modify the hazard analysis and HACCP plan. It is important to note that reassessment does not mean modification of the plan. In other words, reassessment **will not** always lead to modification.

It is important to note that the reassessment is a requirement, but it does not have to be documented by the establishment. Therefore, there isn't a recordkeeping component for either of the 01 or 02 procedure. For the review and observation component of either the 01 procedure or 02 procedure, inspection personnel may observe the establishment's reassessment of the plan.

Establishment Responsibilities

III. B. 4 a. (2) of FSIS Directive 5000.1 requires the establishment to reassess its plan if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding the applicable performance standard (in Table 2 of §310.25(b)(1) or §381.94(b)(1)) on the second consecutive series of FSIS tests for that product (paragraph (b)(3)(ii) of §310.25 or §381.94).

The District Office will provide inspection personnel with further instructions regarding positive *Salmonella* results.

Establishment's Responsibilities

III. B. 4. a. (3) of FSIS Directive 5000.1 requires the establishment to reassess its plan if there was a change that could affect the hazard analysis or alter a HACCP plan (§ 417.4(a)(3)).

Some changes that could affect the hazard analysis are changes in slaughter and processing methods or systems, raw materials, product formulation, packaging, finished product distribution systems, etc.

Establishment's Responsibilities

III. B. 4. b. of FSIS Directive 5000.1 requires the establishment to modify its HACCP plan if a plan reassessment reveals that the plan no longer meets the requirements in §417.2 ©. (§ 417.4(a)(3)).

The establishment **must immediately** modify its HACCP plan when a reassessment reveals that the plan is no longer adequate to meet the HACCP system regulations. Inspection personnel will perform 03A01, the basic compliance check procedure, whenever the establishment modifies its HACCP plan.

Establishment's Responsibilities

III. B. 4 c. of FSIS Directive 5000.1 requires that the individual who performs HACCP reassessments and modifications meet the training requirements in §417.7(b) (§ 417.3(b)(4), 417.4(a)(3), and 417.7(a)(2)).

The establishment is not required to furnish evidence of this training.

Summary

Although inspectors verify all five requirements when performing either the 01 or 02 procedures, at times they will not be able to verify the corrective action and plan reassessment requirements. The corrective action requirement can only be verified if the establishment has had to take corrective action in response to a deviation from a critical limit found by either the inspector or plant employee during monitoring or verification at the CCP. Likewise, the reassessment requirement can only be verified when the establishment experiences a second consecutive *Salmonella* positive result or an unforeseen hazard deviation has occurred. Therefore the majority of the time inspectors will only verify the monitoring, verification, and recordkeeping requirements while performing the 01 and 02 procedures.

Because HACCP is a system, and we must allow the system the opportunity to work, there are the two procedures for verifying the five requirements of the HACCP plan. The 01 procedure is to determine if there is regulatory noncompliance on a random basis. The 02 procedure is to determine if the regulatory requirements of the HACCP plan were met, and the HACCP plan prevented the distribution of adulterated product for a specific lot of product. Therefore, in addition to documenting any noncompliance found during the 01 procedure, the inspector should then perform the 02 procedure on that specific production lot or shipment in which they found the noncompliance during the 01 procedure. That is, when noncompliance is found during the performance of the 01

procedure, inspection personnel should verify the "entire" finished lot of product by performing the 02 procedure.

The 02 procedure is not complete until the lot of product is ready for shipment, the pre-shipment verification has been conducted, and the records have been signed and dated by the plant reviewer. This means that the time elapsed between performance of the 01 procedure and the 02 procedure will vary depending on the length of the process, the time it takes for the plant to perform all the corrective action steps in section 417.3 of the regulations, etc. For example, if noncompliance is found while performing the 01 procedure for a ground beef process, the 02 procedure might be completed at the end of the next shift or the following day. If a noncompliance is found while performing the 01 procedure in a dry cured ham process, portions of the 02 might be completed over the next several days, and the entire 02 procedure might not be completed for days or even weeks. The final step in performing the 02 procedure is the review of the pre-shipment records.

Determining Noncompliance

According to block 8 of the regulatory process model, inspection personnel have to decide whether their findings during the performance of the procedure represent noncompliance with the performance standard and/or regulatory requirement.

As before, they should continue to utilize what is known for a fact and what is reasonable to assume before determining noncompliance exists. Inspectors are going to have to assess what they observe, analyze the facts, decide what the performance standard and/or regulatory requirement is, and use this information to make compliance/noncompliance determinations.

For example:

Let's say that the inspector is verifying the CCP monitoring requirement by performing the review and observation component of the 01 procedure. The establishment's monitoring procedure for the CCP states that the CCP will be monitored every half-hour by a QC technician. It also states that if the critical limit is exceeded the QC technician will notify the QA manager who will initiate corrective action. The QC technician will note his or her action in the comments section of the record. When the inspector measured the critical limit, he or she found that it has been exceeded. The last value recorded was within the established critical limit, and was taken 20 minutes ago. The inspector should allow the opportunity for the establishment's HACCP plan to work. Therefore, part of the 01 procedure would include returning after the next monitoring check to observe the QC technician's findings and actions.

If a measurement taken at the CCP exceeds the established critical limit, the establishment is not meeting the performance and/or regulatory standard defined in its HACCP plan. However, as long as both the QC technician and QA supervisor take the corrective actions described in the HACCP plan, there is no noncompliance.

The establishment must be given adequate time to institute corrective action for noncompliance prior to shipment of the product. The establishment official performing the pre-shipment verification should not sign and date the HACCP records until all corrective actions have been completed to bring the establishment into compliance. The pre-shipment review is the final step in the establishment's HACCP system. FSIS must allow the establishment's system the opportunity to work.

What is noncompliance then? Noncompliance is failure to meet any HACCP regulatory requirement, i.e., monitoring, verification, recordkeeping, corrective action and reassessment. For a HACCP plan, noncompliance exists when either the establishment is not implementing their HACCP plan or when their HACCP plan fails to prevent the production or shipment of adulterated product. In our example, there was no noncompliance, because even though a critical limit was exceeded, the monitoring requirement was met and the appropriate corrective actions were taken.

Let's take our example to the next step. In our example, let's say that the QC technician did not detect the deviation during CCP monitoring. The QA manager did however detect it on verification of the CCP. In this case, even though the establishment did ultimately detect the deviation, the monitoring requirement itself was not met, and therefore there is noncompliance.

Let's take our example to the final step. Let's say in our example the QC technician did not detect the deviation during monitoring. The QA manager did not detect the deviation during verification. But, the HACCP supervisor did detect the deviation during the pre-shipment review and the establishment took appropriate regulatory action. Again, although the establishment did detect the deviation, they failed to meet the monitoring and verification requirements, therefore there is noncompliance.

The next decision to be made in the regulatory process model is whether the noncompliance represents a system failure. This is block 9 of the model.

When inspection personnel find noncompliance, they will need to determine if the system has failed. For HACCP, the regulations 417 define a system failure as an inadequate system.

To determine if the HACCP system is inadequate, the questions the inspector should answer are:

- **Did the establishment review the records associated with production of the product?**

This review should have included determination that all critical limits were met and, if appropriate, corrective actions were taken, including proper disposition of product. If the establishment has not performed the pre-shipment review, then they have not met the regulatory requirements (417.5©). Therefore, the inspector **is unable** to make the determination that the establishment **is not** producing adulterated product, and therefore the HACCP system is inadequate.

The determination of an inadequate system in this case could only be determined by performing the 02 procedure.

- **Was adulterated product produced or shipped?**

The IIC has determined that the HACCP system **did not** prevent the production or distribution of adulterated product. Specifically, the establishment failed to meet a critical limit for a CCP and did not take the corrective actions as per 417.3. of the regulations. If the inspector is able to make this determination, and the establishment has performed their pre-shipment review, then the HACCP system is inadequate.

The determination of an inadequate system in this case could only be determined by performing the 02 procedure. Although, keep in mind, the inspector could have performed the 02 procedure in response to noncompliance found during the 01 procedure.

- **Is there noncompliance with the same root cause?**

In other words, is the same and/or related noncompliance occurring due to the negligence, ineffective method, or incomplete execution by the plant? (FSIS Directive 5000.1 III. C. 2.) If yes, it is possible that an inadequate system exists. There is still no magic number to determine when a systems failure exists due to the same and/or related noncompliance. The NRs should document ongoing failures of the plant's implementation of the HACCP plan and/or execution of effective immediate and further planned actions to bring themselves back into regulatory compliance. Professional analysis must be used when making this determination. Inspection personnel will want to be certain that their documentation made the linkage to the previous noncompliance. They might look at previous NRs noncompliance trend indicators to help make this linkage. If they are able to make this determination and the documentation supports it, then an inadequate system exists.

In cases of noncompliance such as plan documentation, monitoring procedures and methods, or verification procedures and methods that **are not** an inadequate system, the noncompliance will be documented on an NR with the appropriate trend indicator marked. The 01 procedure is specifically designed to determine if regulatory requirements are met. The appropriate noncompliance trend indicator would be marked on the NR, and if the same and/or related noncompliance are occurring due to the negligence, ineffective method, or incomplete execution by the plant, it is possible that these may lead to the determination of an inadequate system.

Documenting trends, could also occur while performing the 02 procedure. The inspector will document the trend(s) when an establishment fails to meet a HACCP regulatory requirement, even if the establishment makes this determination and performs any necessary corrective actions prior to shipping the product. For example, if while performing the 02 procedure, inspection personnel determine that the establishment had a deviation from a critical limit at monitoring, but the establishment discovered the deviation during their verification and took the corrective action according to their plan,

then the inspector would document this as noncompliance with the monitoring requirement. Because in this case the system has in fact worked, you might be asking why we are documenting this on an NR. We are documenting on the NR as a means of documenting the trend.

The determination of an inadequate system in this case could be determined by performing the 01 or 02 procedure.

- **Has the establishment met the basic regulatory requirements?**

  If the establishment is not implementing all or some of their program, then they have not met the basic regulatory requirements. For example, if an establishment is not maintaining **any** records associated with their HACCP plan, the establishment is not monitoring critical limits at any CCP, the establishment did not reassess the HACCP plan when required, or the establishment did not modify their HACCP plan when it no longer meets the requirements—then the establishment has not met the regulatory requirements. Therefore, the inspector **is unable** to make the determination that the establishment **is not** producing adulterated product, and therefore the HACCP system is inadequate. In these cases, the HACCP system would be considered inadequate for not meeting the Basic regulatory requirements. This noncompliance would be documented under the Basic procedure code 03A01.

The determination of an inadequate system in this case could be determined by performing the 01 or 02 procedure.

Enforcement Action

If inspection personnel have determined that there is an inadequate system, they should follow the enforcement action in Part Two of FSIS Directive 5000.1 III. C.1. This action is:

- Withhold inspection and notify the establishment. Provide plant management a copy of the NR. Notify the DO of actions taken. The DM will assign a CO who will visit the establishment and initiate a case file. The DM will provide instructions for enforcement actions from this point. (The action is identical to that which is taken if the establishment fails to meet the basic regulatory requirements.)

It is important to reiterate that the inspection personnel are to contact the **District Office** in cases of a withholding action due to a system failure.

If the inspector is not able to determine that there is a system failure then, the enforcement action is according to Part Three of FSIS Directive 5000.1 III.C. 2.:

- Take official control action as appropriate;

- Advise establishment management by providing a copy of the NR that documents the noncompliance finding(s);

- Complete documentation of establishment action(s) to bring itself into compliance (see FSIS Directive 5400.5); and

- Notify the DO if the establishment does not bring itself into compliance.

Misrepresentation of Records

If there is a HACCP system failure involving the production or shipment of adulterated product, in which misrepresentation of records is suspected, inspectors must withhold inspection and deal with the adulterated product first, and then deal with the misrepresentation issue. Public health and safety *always* takes precedence over any other activities.

If, at any time, FSIS inspection personnel suspect that a plant has engaged in any illegal activity (e.g., falsified required records; offered for sale, sold or transported adulterated or misbranded meat and poultry products in commerce), they will report the alleged violations to the appropriate District Enforcement Operations Official.

Once the Compliance Officer arrives at the plant, he or she will want to review your Noncompliance Record files to develop a case history. This history will aid the District Manager to either sustain current action or take further regulatory action.

When the Agency proceeds with regulatory action, the case file is presented as official evidence. Your documentation must be written so that legal authorities can understand the seriousness of the noncompliance. Your documentation must support regulatory actions. This is the reason your documentation is so important. The Compliance Officer will go through your documentation looking for linkages or recurring noncompliance to prove that the plant does not have proper control over its processes. The Compliance Officer will stress these points in the case file.

In addition to the documents, the Compliance Officer will take a statement from you. This is important, because it establishes you as a field expert. It allows your thought process to be captured in writing for legal authorities to review and understand without interviewing you at the time of the review. Your statement also demonstrates that you are working within the scope of your employment if later indemnification occurs. Keep in mind that Compliance needs your help to build a case.

Finally, suspension and withdrawal actions are subject to Department and Agency supplementary guidelines and rules of practice. You will receive specific instructions on appropriate in-plant controls on a case-by-case basis from the District Office.

Noncompliance Documentation

Recording Noncompliance

All noncompliance will be documented on an NR with NR Continuation Sheet(s) attached as appropriate. The most appropriate trend indicator will be marked on the NR.

Describing Noncompliance

Noncompliance must be accurately described in block 10 of the NR. The NR is an official record used by the inspector to document noncompliance. All information related to noncompliance must be included when describing noncompliance. Since NRs may be used to support an enforcement action, they must be written in a manner that will allow anyone reading the narrative to accurately "visualize" noncompliance. If additional space is needed to describe noncompliance, an NR Continuation Sheet should be used, and a notation to that effect should be made in block 10. NR Continuation sheet(s) should be attached, as appropriate.

Supporting Information

When documenting noncompliance, it's important to reference supporting documentation. Always cite the regulation (e.g., 417.3) which was violated. Include the page and/or part number of the establishment's HACCP plan when those plan requirements are not met. Always cite the date and the name and/or number of the plant record when describing any noncompliance connected with HACCP records. **From an enforcement perspective, it is vital that previous noncompliance occurring as a result of the same and/or related negligence, ineffective methods or incomplete execution i.e., root cause, be included in the documentation.** This can be accomplished by referencing the NR numbers and dates. When citing these recurring noncompliance, also record the failure of the establishment's failure to implement or execute effective immediate or further planned actions as documented on the previous NRs.

Establishment Immediate and Further Planned Actions

Blocks 12 and 13 respectively have been provided for the establishment to identify verbal or written immediate and further planned action to bring themselves back into compliance with the regulation requirements.

Inspection personnel need to determine that the immediate and further planned actions bring the establishment back into compliance with regulatory requirements. **Official control action will be maintained if the inspector can not determine that the plant is in compliance with regulatory requirements from the identified actions.**

1. What are the five regulatory requirements that the ongoing operations of the establishment's HACCP system must meet?

2. What is the purpose of the 01 inspection procedure for HACCP?

3. What is the purpose of the 02 inspection procedure for HACCP?

4. What are the two components of the other compliance/noncompliance procedures for HACCP?

5. If noncompliance is determined while performing the 01 HACCP procedure, what is the appropriate action?

6. What requirements must the establishment meet if they determine there is a deviation from a critical limit?

_____

_____

_____

_____

7. Will FSIS document noncompliance when the establishment fails to meet one of the regulatory requirements, but the system is not determined to be inadequate?

_____

_____

_____

_____

8. When noncompliance is determined, the next decision is whether there is an inadequate system. What are the 4 questions used in making this determination?

_____

_____

_____

_____

9. What is the appropriate enforcement action if the system is determined to be inadequate?

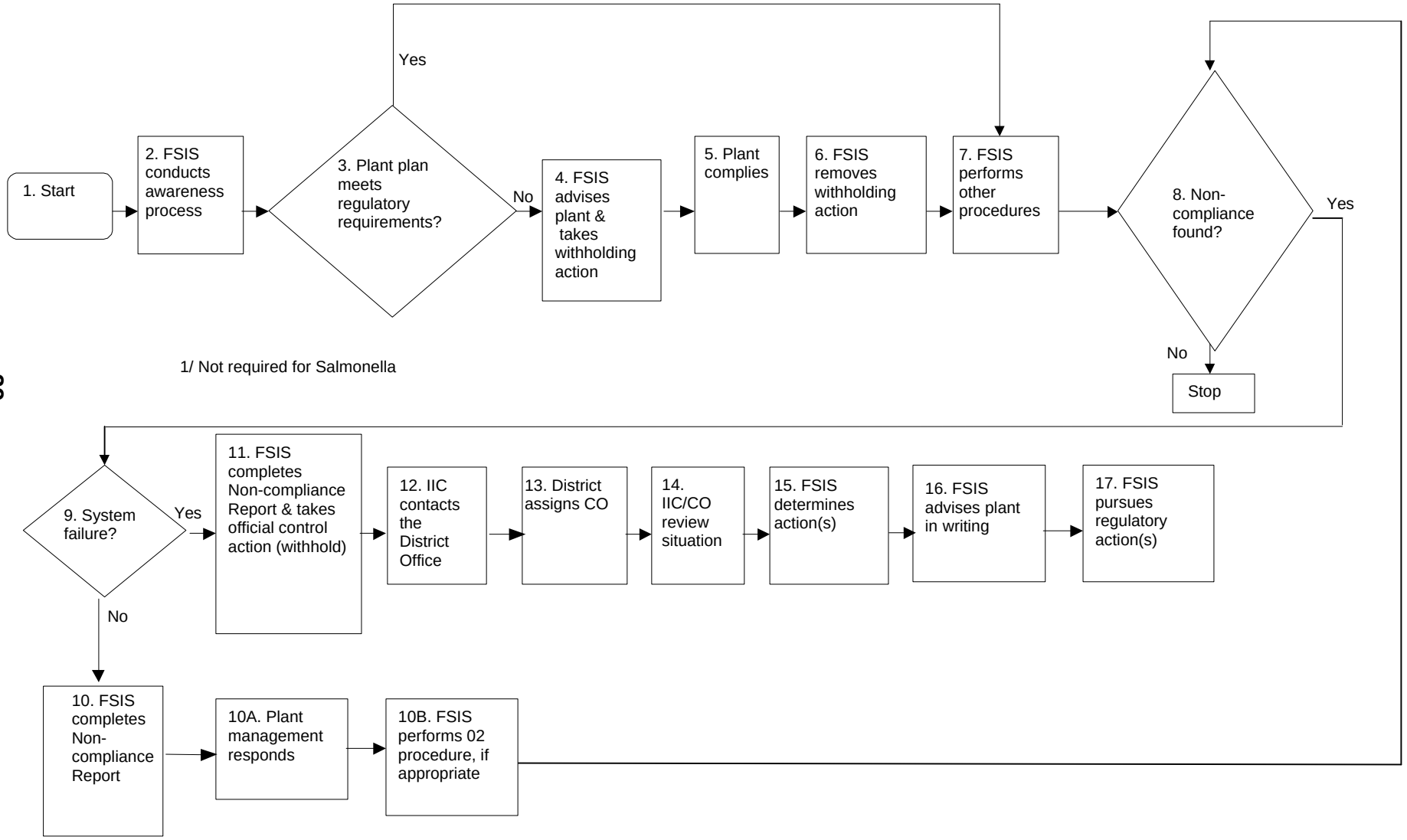
_____

_____

_____

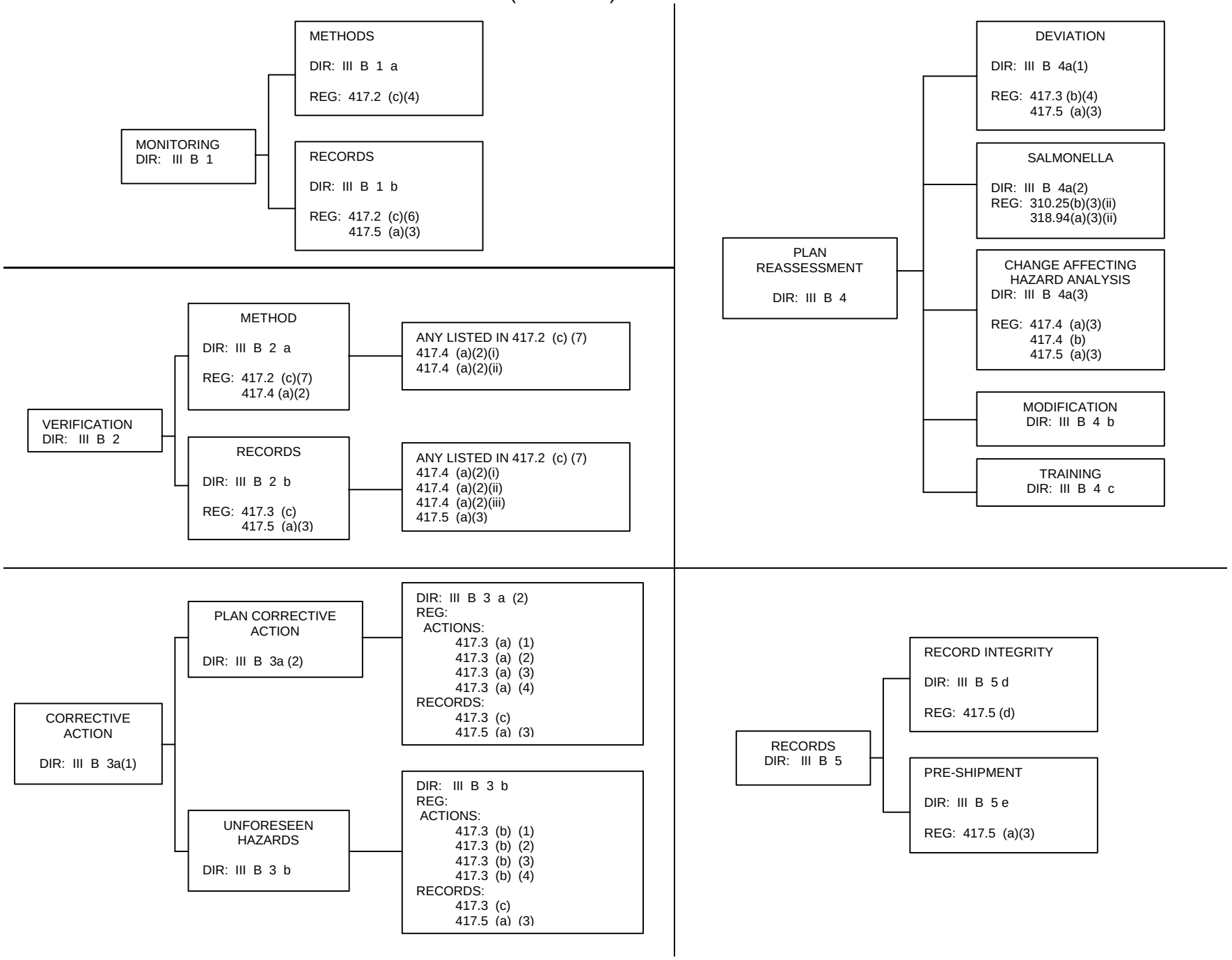
_____

REGULATORY PROCESS FOR HACCP- BASED INSPECTION



1/ Not required for Salmonella

INSPECTION PROCEDURES 03(B THRU J)02 -- WORK IDENTIFICATION FLOWCHART



INSPECTION PROCEDURES 03(B THRU J)01 -- WORK IDENTIFICATION FLOWCHART